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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,923

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Gianfranco De Paoli Ambrosi

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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT

PAPER NUMBER

1619

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/557,923	<b>Applicant(s)</b> DE PAOLI AMBROSI, GIANFRANCO	
	<b>Examiner</b> JYOTHSNA A. VENKAT	<b>Art Unit</b> 1619	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-23,25-31,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23, 25-31 and 41-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt is acknowledged of amendment and remarks filed on 3/8/10. Claim 24 and non-elected claims 32-40 have been cancelled and claims 41-42 have been added as per applicants' amendment dated 3/8/10.

#### **Status of claims**

**Claims 1-20, 24 and 32-40 are cancelled.** Claims 21-23, 25-31 and 41-42 are pending in the application.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-23, 25-31 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

Claims 21-23, 25-28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 4,082,881 ('881).

#### **Claim analysis**

Claims are drawn to composition. Preamble and intended use does not carry any patentable weight as the claims are drawn to compositions and not to method of use.

Patent '176 teaches compositions for healing damaged skin comprising claimed trichloroacetic acid (abstract). Patent at col.1, ll 32-34 teaches trichloroacetic acid peel for damaged skin. Patent at col.3, ll 5-8 for the amount of trichloroacetic acid which is from 10- about 50 % and this meets the limitations of claims 22-23 for the amount of trichloroacetic acid. Patent under claim 2 is claiming trichloroacetic acid and under claim 11 is claiming the amount of trichloroacetic acid. Patent '176 also teaches using surfactants (also know as emulsifiers

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belonging to excipients of claims 27- 28) at col.3, line 34 through col.4, line 16. Patent under claim 10 is claiming surfactant and under claim 11 is claiming the amount of surfactant. Patent at col.4, ll 61-65 teaches glycerin and at col.5, ll 1-10 teaches glycols drawn to claimed solvents (claims 27-28). Claim 20 of patent is to water (solvent of claims 27-28). Patent at col.5, ll 14-17 teaches adding antioxidants so that oxidative destruction of the composition is prevented. Claim 21 of patent is to antioxidant and claim 22 of patent is to preservatives (claims 27-28 under excipients). The difference between the patent and instant application is patent does not teach dimethyl isosorbide.

Patent '881 teaches topical and other pharmaceutical formulations containing isosorbide carrier. Patent '881 under abstract teaches isosorbide as solvent and at col.2, ll 14 teaches claimed dimethyl isosorbide and at col.2, ll 17-21 teaches the amount which is 0.5-95%. Both the patents teach amount of keratolytic agent and dimethyl isosorbide which meet limitations of claims 22-23 and thus meet the ratio range claimed in claim 21 and claim 41.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare peel compositions by using trichloroacetic acid which is taught and claimed by patent '176 and add solvent dimethyl isosorbide taught by patent '881 with the reasonable amount of success that the dimethyl isosorbide when used as vehicle is capable of solubilizing the keratolytic agent trichloroacetic acid and the solvent being dermatologically beneficial, stable and pharmaceutically acceptable for topical formulations. This is prima facie case of obviousness.

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Claims 29-31 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 4,082,881 ('881) as applied to claims 21-23, 25-28 and 41 above, and further in view of WO 94/05301 ('301).

The patents cited above do not teach claimed dimethyl sulfone. However WO '301 teaches dermatitis compositions using salicylic acid and dimethyl sulfone. Salicylic acid is also a keratolytic agent. Thus WO '301 teaches the combination of keratolytic agent and dimethyl sulfone. See the abstract. See page 7 under table for MSM, which is same as dimethyl sulfone since dimethyl sulfone is also known as methyl sulfonyl methane. The weight percent is 10% and this is within the weight percent claimed in claim 30 and this weight percent is covered by claim 31.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare peel compositions by using trichloroacetic acid which is taught and claimed by patent '176 and add solvent dimethyl isosorbide taught by patent '881 and add dimethyl sulfone taught by WO document with the reasonable amount of success that the dimethyl isosorbide when used as vehicle is capable of solubilizing the keratolytic agent trichloroacetic acid and the solvent being dermatologically beneficial, stable and pharmaceutically acceptable for topical formulations and adding dimethyl sulfone as the vehicle so that prolonged therapeutic effect of the active ingredient like tri fluoro acetic acid can be achieved. This is prima facie case of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, EYLER YVONNE (BONNIE) can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /  
Primary Examiner, Art Unit 1619